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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/571,311

03/09/2006

Wilhelm Wurst

27234U

6257

34375 7590 12/28/2009

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EXAMINER

SOROUGH, ALI

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

12/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/571,311	Applicant(s) WURST ET AL.	
	Examiner ALI SOROUGH	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 43-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>082609</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Receipt

Applicant response filed on 08/26/2009 to the Office Action mailed on 04/01/2009 is acknowledged.

Status of the Claims

Claims 22-42 are cancelled, claim 1 is currently amended and claims 45 and 46 are newly added. Therefore, claims 1-21 and 43-46 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.

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3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-16, 19, 20, 43, 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oliver et al. (US Patent 6120752, Published 09/19/2000).

Applicant Claims

Applicant claims a method for treating a respiratory disease in patient that is a child comprising administering a dose of a composition comprising ciclesonide in an amount from 20 to 200µg.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Oliver et al. teach a aerosol formulation for oral and/or nasal inhalation comprising 4mg/ml of ciclesonide, 0.237mg/ml of oleic acid, 1087.222mg/ml of ethanol, and 1186.0mg/ml of P134a. (See abstract and column 8, Lines 10-20). A metered dose dispensing valve is used to dispense 50 µl of the formulation. (See column 3, Lines 5-16). The formulation is useful as an antiasthmatic. (See column 1, Lines 42-45).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Oliver et al. does not anticipate wherein the patient is a child between the ages of 6 to 12 years. However, Oliver et al. does make treatment of such patients obvious.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the inhalation composition taught by Oliver et al. in patients who are children between the ages of 6 to 12 years. One would have been motivated to do so because Oliver et al. is silent as to the age of the patient receiving the composition, therefore one of ordinary skill in the art would expect that administration of Oliver et al.'s composition to patients of any age would work equally well in treating asthma.

Therefore, if one wanted to treat a child between the ages of 6 to 12 years suffering from COPD and/or asthma one would administer the composition of Oliver et al. With regard to instant limitation of the formulation being applied to the mucosa of claim 46, it is the Examiners position that application via nasal passage as taught by Oliver et al. meets this limitation as the nasal passage is made mucosal tissue. For the foregoing reasons the instantly claimed invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

2. Claims 1-13 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calatayud et al. (UK Patent Application GB 2247680 A, Published 11/03/1992).

Applicant Claims

Applicant claims a method for treating a respiratory disease in patient that is a child comprising administering a dose of a composition comprising ciclesonide in an amount from 20 to 200µg.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Calatayud et al. teach powder for inhalation comprising 0.1g of micronized ciclesonide as (R) or (S) or (RS) diastereoisomers/mixtures and 20mg of lactose. (See abstract and page 32, Lines 34-38). This composition can be used for the treatment of asthma by inhalation of the formulation. (See page 2, Lines 16-20).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Calatayud et al. does not anticipate wherein the patient is a child between the ages of 6 to 12 years. However, Calatayud et al. does make treatment of such patients obvious.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the inhalation composition taught by Calatayud et al. in patients who are children between the ages of 6 to 12 years. One would have been motivated to do so because Calatayud et al. is silent as to the age of the patient receiving the composition, therefore one of ordinary skill in the art would expect that administration of Calatayud et al.'s composition to patients of any age would work equally well in treating asthma. Therefore, if one wanted to treat a child between the ages of 6 to 12 years suffering from COPD and/or asthma one would administer the composition of Calatayud et al. For the foregoing reasons the instantly claimed invention would have been

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent

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Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/

Primary Examiner, Art Unit 1616